**Abstract 562**

**TITLE:** Informed Consent in Microbicides Testing

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**ISSUE:** Evaluating the safety and effectiveness of vaginal microbicides to prevent sexual transmission of HIV/STDs presents a number of practical and ethical challenges for researchers and communities. Testing must occur where women are at substantial risk of HIV, often in the most vulnerable populations. The trial objectives and procedures are complex and can be difficult to understand as well as involving sensitive topics like sexual practices and HIV, a disease that remains stigmatized and deadly. These factors make ensuring truly informed consent and voluntary participation challenging.

**SETTING:** Family planning clinics in South Africa.

**PROJECT:** To address these issues we conducted a pilot study to test the informed consent documents to be used in a Phase II (expanded safety and acceptability) trial in South Africa. To ensure that the informed consent forms are clear and explain the study using language and concepts that are readily understood two focus groups and seven interviews were conducted among family planning clients from the recruitment population. This involved exploring specific language, concepts amount of information, and possible ways to present information, in addition to the formal written consent.

**RESULTS:** The process highlighted a number of challenges: providing essential details of the study without contusing potential participants; finding understandable non-judgmental terms for sexual practices; fairly informing women about potential risk without unduly alarming them; and making clear the scope and limits of researchers and participants obligations.

**LESSONS LEARNED:** Using the information gathered in this study, we determined the need for developing extensive materials to explain the study and the necessity of revising the informed consent documents.

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